

Claims of the Application:

1. (Original) A compound which is a crystalline Form Z of rabeprazole sodium.
2. (Original) The compound of claim 1 having an X-ray diffraction pattern, expressed in terms of 2 theta angles, that includes four or more peaks selected from the group consisting of 4.69 ± 0.09 , 9.07 ± 0.09 , 9.42 ± 0.09 , 11.25 ± 0.09 , 14.71 ± 0.09 , 16.24 ± 0.09 , 17.26 ± 0.09 , 18.52 ± 0.09 , 18.52 ± 0.09 , 19.32 ± 0.09 , 19.63 ± 0.09 , 19.92 ± 0.09 , 20.80 ± 0.09 , 21.48 ± 0.09 , 23.07 ± 0.09 , 24.81 ± 0.09 , 25.70 ± 0.09 , 27.47 ± 0.09 , 30.01 ± 0.09 , 30.65 ± 0.09 , 33.37 ± 0.09 , and 36.95 ± 0.09 .
3. (Original) The compound of claim 2 having an X-ray diffraction pattern expressed in terms of 2 theta angles and obtained with a diffractometer equipped with a Cu K alpha-1 radiation source, wherein said X-ray powder diffraction pattern includes five or more peaks selected from the group consisting of peaks with 2 theta angles of about 4.694, 9.070, 9.417, 11.254, 14.712, 16.241, 17.264, 18.522, 18.522, 19.320, 19.626, 19.920, 20.802, 21.477, 23.073, 24.814, 25.702, 27.470, 30.009, 30.653, 33.365, and 36.950.
4. (Original) The compound of claim 1, having substantially the same X-ray diffraction pattern as shown in Figure 1.
5. (Original) The compound of claim 1, which has an endo-exo pattern with identified peaks of about 106.5 °C and 228.8 °C in its differential scanning calorimetry thermogram.
6. (Currently amended) ~~A composition comprising rabeprazole~~ Rabeprazole sodium as a solid, wherein at least 80 % by weight of said ~~said~~ solid rabeprazole sodium is a crystalline Form Z of rabeprazole sodium.

7. (Original) The composition Rabeprazole sodium of claim 6, wherein at least 90 % by weight of said solid rabeprazole sodium is the crystalline Form Z.

8. (Original) The composition Rabeprazole sodium of claim 6, wherein at least 95 % by weight of said solid rabeprazole sodium is the crystalline Form Z.

9. (Original) The composition Rabeprazole sodium of claim 6, wherein at least 99 % by weight of said solid rabeprazole sodium is the crystalline Form Z.

10. (Original) The composition Rabeprazole sodium of claim 6, wherein said rabeprazole sodium is substantially free of amorphous form, Crystal II, Form X and Form Y of rabeprazole sodium.

11. (Currently amended) A pharmaceutical composition comprising prepared by combining a prophylactically or therapeutically effective amount of the compound of claim 1 and one or more pharmaceutically acceptable excipients.

12. (Original) The pharmaceutical composition of claim 11, wherein said composition is a solid dosage form for oral administration.

13. (Original) The pharmaceutical composition of claim 11, wherein said dosage form is a tablet.

14. (Withdrawn) A pharmaceutical composition comprising a prophylactically or therapeutically effective amount of the compound of claim 1, one or more pharmaceutically acceptable excipients, and one or more antimicrobial compounds.

15. (Withdrawn) The pharmaceutical composition of claim 14, wherein said antimicrobial compound is selected from a group consisting of penicillins including benzylpenicillin, phenoxyethylpenicillin, propicillin, azidicillin, dicloxacillin, flucloxacillin, oxacillin, amoxicillin, bacampicillin, ampicillin, meziocillin, piperacillin, or aziocillin;

cephalosporins including cefadroxil, cofactor, cefalexin, cefalexim, cefuroxim, cefetamet, cefadroxil, ceftibuten, cefpodoxim, cefotetan, cefazolin, cefoperazon, ceftizoxim, ceftaxim, ceftazidim, cefamandol, cefepim, cefoxitin, cefodizim, cefsulodin, ceftriaxon, cefotiam, or ceftnenoxim; aztreonam; loracarbef; meropenem; sulbactam; tetracyclines including tetracycline, oxytetracycline, minocycline, or doxycycline; aminoglycosides including tobramycin, gentamicin, neomycin, streptomycin, amikacin, netilmicin, paromomycin or spectinomycin; amphenicol including chloramphenicol or thiamphenicol; lincomycins; clindamycin; lincomycin; erythromycin; clarithromycin; spiramycin; roxithromycin; azithromycin; colistin; polymixin B; teioplanin; vancomycin; norfloxacin; cinoxacin; ciprofloxacin; pipemidic acid; enoxacin; nalidixie acid; pefloxacin; fieroxacin; ofloxacin; metronidazole; fomycin; fucidic acid; taurolidine; taurultam; and mixtures thereof.

16. (Withdrawn) A method of preventing or treating a disease that is associated with excess gastric acid secretion, comprising administering to a patient in need of said prevention or treatment an effective amount of the compound of claim 1.

17. (Withdrawn) The method of claim 16, wherein said disease is an ulcer, gastroesophageal reflux disease, psoriasis or Zollinger-Eliison Syndrome.

18. (Withdrawn) A process for making a crystalline Form Z of rabeprazole sodium, wherein said process comprising:

- a. providing rabeprazole sodium in an aromatic hydrocarbon solvent;
- b. heating said aromatic hydrocarbon solvent to reflux; and
- c. cooling said solvent until a solid mass separates which is crystalline Form Z of rabeprazole sodium.

19. (Withdrawn) The process of claim 18, wherein said starting rabeprazole sodium is a crystalline form, an amorphous form or a mixture thereof.

20. (Withdrawn) The process of claim 18, wherein said aromatic hydrocarbon solvent is toluene, xylenes or mixtures thereof.
21. (Withdrawn) The process of claim 18, wherein said aromatic hydrocarbon solvent is toluene.
22. (Withdrawn) The process of claim 18, wherein said rabeprazole is provided in said aromatic hydrocarbon solvent in a ratio between about 1:3 and about 1:20.
23. (Withdrawn) The process of claim 22, wherein said ratio is between about 1:3 and about 1:10.
24. (Withdrawn) The process of claim 22, wherein said ratio is about 1:4.
25. (Withdrawn) A crystalline Form Z of rabeprazole sodium, which is prepared according to the process of claim 18.
26. (New) The compound of claim 1, having substantially the same differential scanning calorimetry curve as shown in Figure 2.
27. (New) The compound of claim 1, having a melting point about 224-230°C.